



UNITED STATES PATENT AND TRADEMARK OFFICE

Cen

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,304	01/14/2004	Bruce W. Anderson	GP106-10-CN2	5359
21365 7590 01/11/2008 GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE Mail Stop #1 / Patent Dept. SAN DIEGO, CA 92121			EXAMINER RAMDHANIE, BOBBY	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 01/11/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com
kelleec@gen-probe.com
belindao@gen-probe.com

Office Action Summary

Application No.

10/758,304

Applicant(s)

ANDERSON ET AL.

Examiner

Bobby Ramdhanie, Ph.D.

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/13/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/13/2007 have been fully considered but they are not persuasive. The following are reasons why:
2. Applicants state in their Prior Art rejections that the cap of Claim 1 is not anticipated by Koch et al because the recited striations are not openings in a cap wall. Examiner takes the position that a synonym for striation can be defined as a "slit" according to FreeThesaurus.net. Examiner takes the position that Koch et al does anticipate the cap of Claim 1. Furthermore, another synonym for striation is a band (rib) or a groove. In each case, whether it is a striation, slit, band, rib, or groove, all structures have a physical thickness which can be measured.

Response to Amendment

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 13, 17, & 19 rejected under 35 U.S.C. 102(b) as being anticipated by Koch et al (US5578272). Regarding Claim 1, Koch et al teaches a plastic cap comprising (Figures 6-10; Column 3 lines 53-67): A). An opening defined by a an annular top; and a downwardly tapered inner wall positioned beneath the opening and

structurally (Figure 10) interrelated to the top wall, the inner wall including a plurality of radially extending striations formed therein, wherein each of the striations has a thickness (Figure 10 Item Numbers 94 & 95). Examiner takes the position that slots 94 and 95, which are made by a blade, define striations.

3. For Claim 2, Koch et al teaches the cap of claim 1 further comprising means for fixedly associating the cap with an open end of a fluid-holding vessel (Figure 10 Item number 83 & Figure 10 Item Number 89).

4. For Claim 3, Koch et al teaches the cap of claim 1, wherein the inner wall depends from about the top wall (Figure 10).

5. For Claim 4, Koch et al teaches the cap of claim 1 further comprising a lower annular wall joining the top wall to the inner wall (Figure 9; Items 84 & 85).

6. For Claim 5, Koch et al teaches the cap of claim 1 further comprising an upper annular wall extending upwardly from the top wall (Figure 7).

7. For Claim 6, Koch et al teaches the cap of claim 5 further comprising a wick contained within the cap (Column 4 lines 5-6). Examiner takes the position that a wick is anything that may wipe off or "wick" the outside surface of the pipette used to puncture the seal. The metal sealing foil can define a wick, in its broadest reasonable interpretation.

8. For Claim 7, Koch et al teaches the cap of claim 6, wherein the wick is positioned substantially above the top wall (Column 4 lines 5-6 & Figure 6 Item number 98).

9. For Claim 9, Koch et al teaches the cap of claim 6 further comprising a seal affixed to a top surface of the upper annular wall (Column 4 lines 5-6 & Figure 6 Item number 98).
10. For Claim 13, Koch et al teaches the cap of claim 1, wherein the inner wall is conically shaped and has an angle of from about 25° to about 65° relative to the longitudinal axis of the cap (Column 3 lines 64-67).
11. For Claim 17, Koch et al teaches the cap of claim 1, wherein the striations are formed in an inner surface, an outer surface or both the inner and outer surfaces of the inner wall (Figure 9).
12. For Claim 19, Koch et al teaches the cap of claim 1, wherein each of the striations comprises a radially extending groove in the inner wall (Figure 10 Items 94 & 95).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al in view of Percarpio (US4338764). Regarding Claim 8, Koch et al teaches the cap of Claim 6. Koch et al teaches that the wick is foil. Koch et al does not teach that the wick is a pile fabric. Percarpio et al teaches this feature (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a pile fabric. It would have been obvious to one of ordinary skill at the invention was made to modify Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36). In addition, it is well known in the art that foil seals react violently with many

acids and other corrosive materials. It would have been obvious to use a pile fabric which is non-reactive to the type of corrosive material that is stored in the container.

16. Claims 10-12, 14-16, 18, 20, 22-24, & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al. Regarding Claims 10-12 & 22-24, Koch et al teaches the cap of Claim 6. Koch et al does not explicitly teach the specific amount of pounds force to needed to penetrate the wick and inner wall with a plastic pipette. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Koch et al with the range of pounds force needed to puncture the wick and inner wall since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routing skill in the art. *In re Aller*, 105 USPQ, 233.

17. For Claims 14-16, Koch et al teaches the cap of Claim 1. Koch et al does not teach wherein each of the striations of the inner wall has a rounded bottom or that the thickness ratio between non-striated and striated portions of the inner wall is in the range of about 10:1 to about 1.25:1, or wherein the average thickness of striated portions of the inner wall is between about 0.002 inches and about 0.008 inches, and wherein the average thickness of non-striated portions of the inner wall is between about 0.01 inches and about 0.02 inches. It would have been an obvious to modify the striations of Koch et al with a round bottom since this would only be a design choice and an obvious variant of a slit that would work equally as well

18. For Claim 18, Koch et al teaches the cap of Claim 17. Koch et al further teach that the cap has at least two striations. Koch et al does not teach that the inner wall of

the cap has between 3 and 12 of the striations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Koch et al to include any number of striations because this would be an obvious variant and a design choice as well as aid in the decrease of force needed to puncture the inner wall.

19. For Claim 20, Koch et al teaches the cap of claim 1. Koch et al does not teach one or more radially extending ribs formed on an inner surface of the inner wall, each rib being positioned between a pair of adjacent striations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the type of striation on the inner wall to be in the form of a groove or a rib to reinforce weakened openings around the slits to prevent the entire inner wall from ripping or tearing and/or be a design choice. Examiner is giving the word striation its broadest reasonable interpretation. Since a band or rib and slit are synonyms for a striation, it would have been obvious to one of ordinary skill to come up with this design with undue experimentation.

20. For Claim 26, Koch et al teaches a leak-proof collection device formed by fixedly associating the cap of claim 2 with an open end of a fluid-holding vessel (Figure 1).

21. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al in view of Sandhage (US2906423). Koch et al teaches all of the claim limitations of Claim 1. Koch et al does not teach the cap of Claim 1, wherein an inner surface of the inner wall is at least partially coated with a lubricant. Sandhage teaches this feature. Sandhage teaches a cap puncturable by a polyethylene needle (Figures 1-3). Sandhage also teaches that a lubricant may be added to the surface of the cap (Column

2 lines 48-52). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Sandhage because according to Sandhage, addition of the lubricant to the stopper will allow for ease of insertion (of the needle) and the lubricant tends to fill up the cut slit thereby preventing the entry of contaminating microorganisms and also lubricating the entry of the polyethylene needle through the conical well into the interior of the bottle (column 2 lines 52-58)

22. 25. Canceled

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claim1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 & 1-11 of copending

Applications Nos. 11/928866 & 11/926665 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending applications claims a cap comprising top wall, inner conical wall, striations either on the outside, inside or on both sides of the inner wall radially extended, and seals. Both applications claim the same structural dimensions and limitations regarding how the cap is designed and components it is made out of.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

1. Claim 26 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-22 of copending Application No. 11/928866. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application includes collection device which is fixedly associated with a fluid holding vessel. Both applications claim the same structural dimensions and limitations regarding how the cap is associated with the fluid holding vessel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Information Disclosure Statement

1. The information disclosure statement filed 01/24/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The non-patent literature publication "PACE 2 Specimen Collection Guide" (Gen Probe Incorporated Product Literature, 1996) has not been considered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

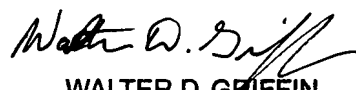
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
10/758,304
Art Unit: 1797

Page 11

BR

A handwritten signature in black ink, appearing to read "Walter D. Griffin", with a stylized flourish at the end.

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER